EXHIBIT 10

United States Patent [19]
Swanson

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[45] **Date of Patent:** **Oct. 15, 1985**

[54] **ACCELERATED HEART VALVE TESTING APPARATUS AND METHODS**

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[73] Assignee: **Dynatek, Inc.**, St. Louis, Mo.

[21] Appl. No.: **641,870**

[22] Filed: **Aug. 17, 1984**

[51] **Int. Cl.**^{4} **G01N 3/36**
[52] **U.S. Cl.** **73/37**; 73/168; 73/812
[58] **Field of Search** 73/3, 168, 48, 46, 812

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,381,663 5/1983 Swanson 73/37
4,450,710 5/1984 Nettekoven 73/37

Primary Examiner—Stewart J. Levy
Assistant Examiner—Hezron E. Williams
Attorney, Agent, or Firm—Kalish & Gilster

[57] **ABSTRACT**

Apparatus and methods for durability (fatigue) testing of prosthetic heart valves or other check valves. The apparatus is circular in plan and includes a test fixture in which the valves are circularly arranged, located with communicating passages, such passages communicating with bellows closed at one end. The bellows are carried by a swash plate journalled to a motor by a coupling providing an adjustable tilt axis. The tilt axis determines the amplitude of the motion or flow of the fluid, as the bellows alternately expand and contract. A central bypass chamber includes orifices which are selectively varied in effective cross section to control an amount of the test fluid which bypasses the test samples, thereby determining fluid pressure differential across the sample valves. Fluid in the apparatus can be heated by an electric heater to temperatures similar to human blood, a temperature probe monitoring the temperature for its control. A pressure tap monitors the fluid pressure for shutting down the apparatus if abnormal pressures or leaks are developed. Several prosthetic heart valves, e.g., two, four, six, eight, etc., are held by the fixture at the same time for life testing at relatively high cyclic rates.

14 Claims, 5 Drawing Figures

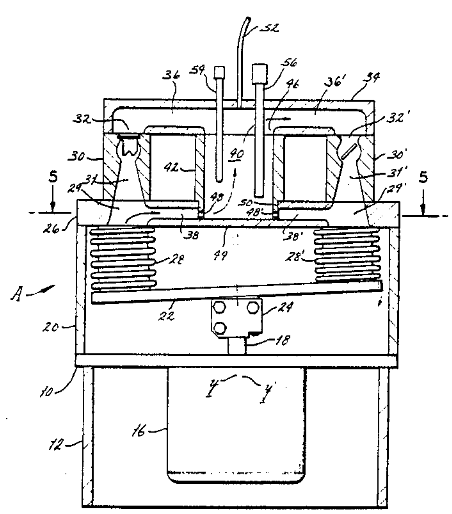
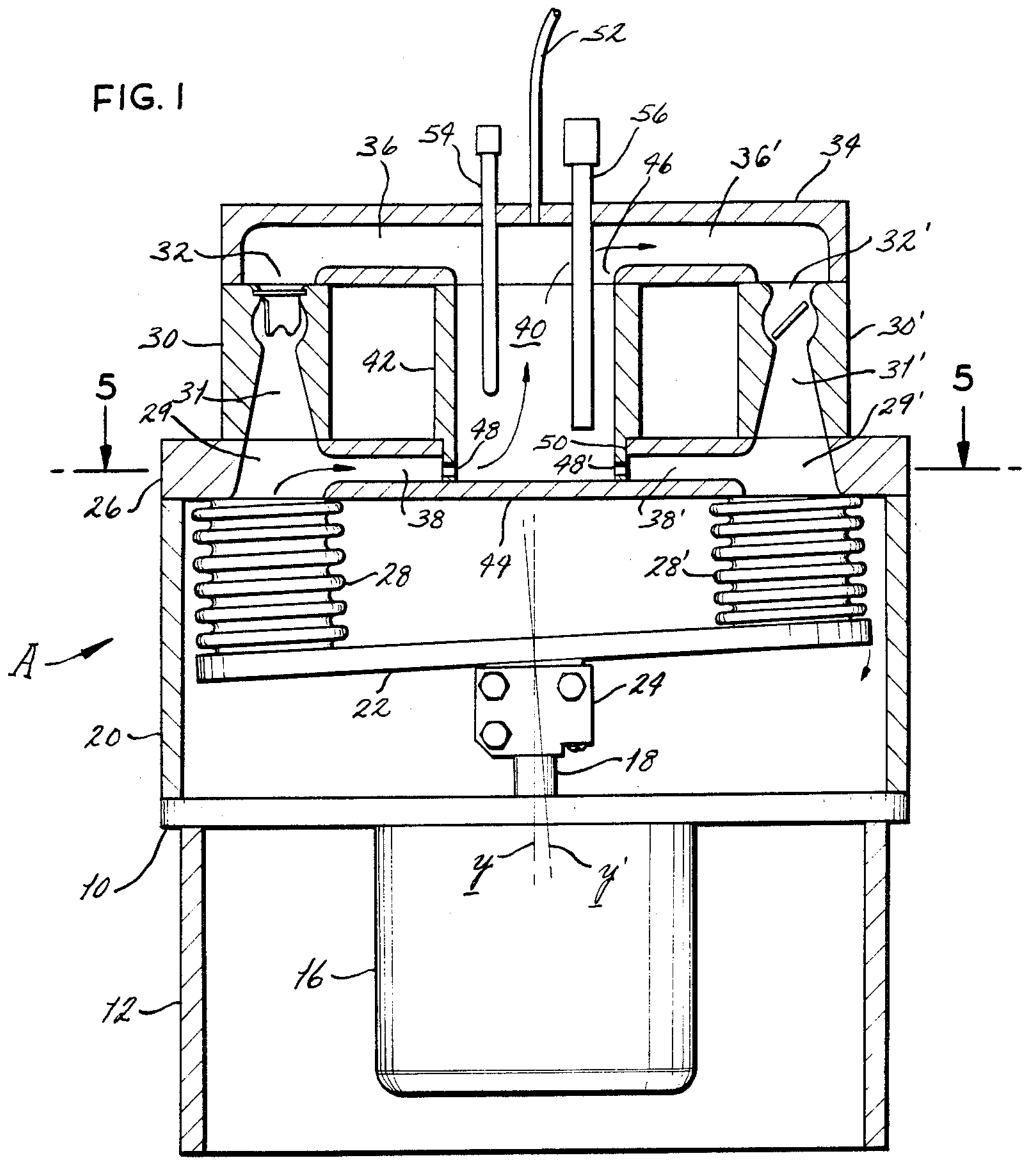


FIG. 1



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36'
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22
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18
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y'
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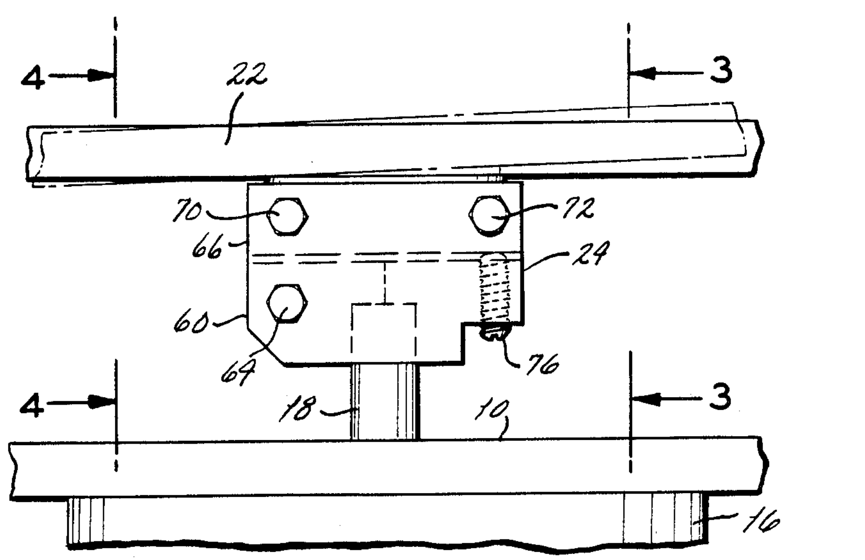
12

FIG. 2



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70
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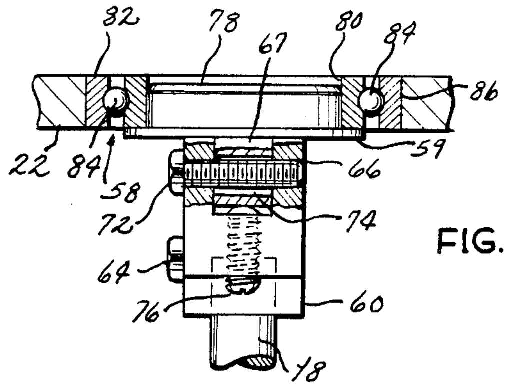
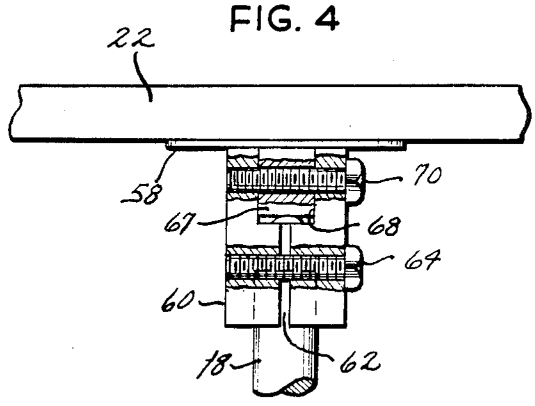


FIG. 3

FIG. 4



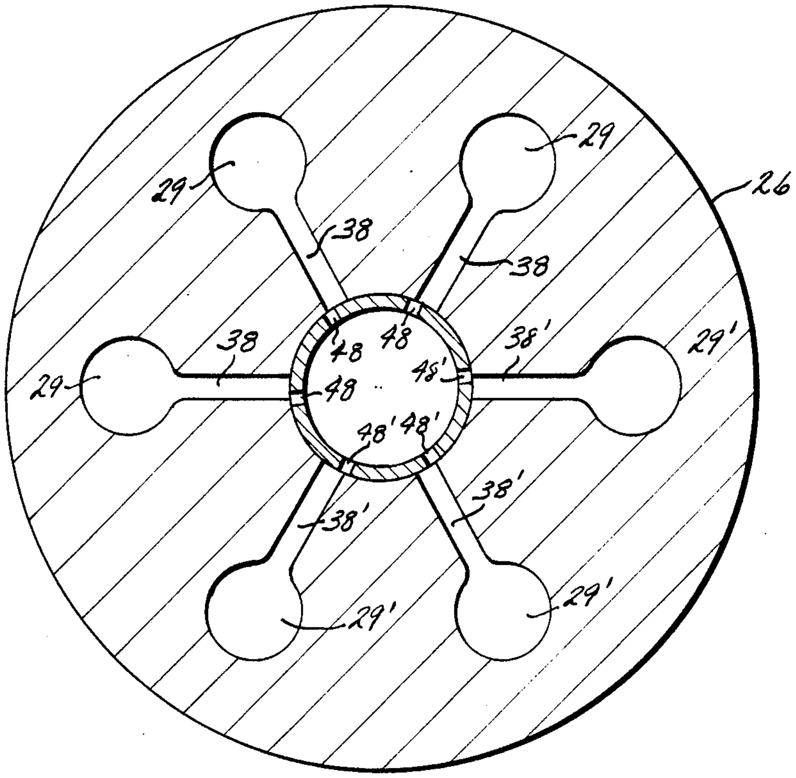


FIG. 5

ACCELERATED HEART VALVE TESTING APPARATUS AND METHODS

BACKGROUND AND SUMMARY OF THE INVENTION

The present invention relates to the testing of prosthetic heart valves, or similar valves.

Representative of the prior art is Swanson U.S. Pat. No. 4,381,663, in which are set forth apparatus and methods by which test samples such as heart valves are tested in a closed fluid environment by oscillating flow of a bellows-actuated fluid oscillator.

A particular need arises in the durability-fatigue testing of biological tissue prosthetic heart valves. To be tested properly such heart valves may be conducted in a sterile human blood plasma environment at normal body termperature, 37° C.

In the testing of such heart valves, it may be desired to carry out a testing of several at the same time. The valves may vary from valve to valve, and it is desirable to be able to test each under the same operating conditions so as to achieve a desired degree of control for comparative purposes.

Accordingly, it is an object of the present invention to provide an improved apparatus for testing of heart valves by the provision of a system making closed durability, or fatigue tests on a number of different samples at the same time.

Specifically, an object of the present invention is the provision of such apparatus and methods for testing of prosthetic heart valves in a sterile blood plasma, or other fluid environment at body temperature.

It is another object of the invention to provide such testing apparatus and methods for carrying out the testing of heart valves in a preselected fluid medium at a desired temperature.

It is also an object of the present invention to provide such apparatus wherein testing may be carried out automatically and without supervision with assurance that testing of the apparatus will automatically terminate in the event of a failure, undesired condition, excessive temperature or the like.

Yet another object of the invention is the provision of such testing apparatus and methods which provide repetitive stressing of the heart valve at a high frequency which may be considerably greater than that at which the sample under test would normally be flexed in use, thereby greatly accelerating the life testing of such sample.

Another object of the invention is the provision of such testing apparatus and methods wherein a number of different valves being tested at one time may be varied from test to test, and wherein the number of samples under test does not influence the test conditions in a deleterious or disadvantageous way.

The invention has as another object the provision of such testing apparatus and methods which are extremely compact and which minimize the volume of test fluid being utilized, as well as minimizing the cubage of the apparatus, and providing apparatus which operates with extreme efficiency and little input power.

Yet another object of the invention is the provision of such test apparatus and methods which allow substantial variation in the amplitude of the stresses applied to the sample during test, and permitting the amplitude to be very readily and easily changed without disturbance of other aspects ot the test, while providing nevertheless testing apparatus and methods which permit a wide range of testing conditions, including different termperatures, pressures, frequencies and stresses.

Among still other objects of the invention include the provision of such testing apparatus which: provides testing in a completely sealed fluid environment; economizes in the use of test fluids; provides extremely high test visablility and ease of insertion and removal of test samples and high accessibility thereof; permits test fluid to be easily filled, emptied and/or removed, and facilitates cleaning of the apparatus.

Briefly, valve testing apparatus for testing of test samples, i.e., valves, in accordance of the invention by application of repeated oscillatory forces produced by fluid motion relative to the sample includes a chamber for receiving a plurality of test samples, the chamber being such as to define individual fluid flow passages communicating with respective test samples for directing an oscillating flow of fluid of such test samples. Plural bellows are connected with each of the respective fluid flow passages, with which they are arranged in a circular pattern, and a swash plate is positioned below the bellows, with means for rotatably driving the swash plate oscillatorily to provide corresponding alternate expansion and contraction of the bellows. A further fluid passage is connected with the test samples for providing a fluid path extending from one of the bellows, into the test sample, through the further fluid passage, through another test sample, and to another bellows, by the opposite side of the swash plate. The swash plate, with adjustable tilt axis, causes alternate contraction and expansion of the bellows on opposite sides of the swash plate to alternately expose the test samples to oscillatory fluid forces.

A bypass passage carries the flow while a valve is closed. The inertial reaction of the fluid in this passage during flow acceleration determines the pressure loading on the valve.

An electric heating device and a temperature probe are utilized for controlling the temperature of the fluid in the apparatus, such as to provide, for example, tests under conditions typical of the human blood plasma environment at 37° C.

Other objects and features will be in part apparent and in part pointed out hereinbelow.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a vertical cross-section of testing apparatus constructed in accordance with and embodying and carrying out the present invention.

FIG. **2** is an enlarged side view of portions of a certain swash plate rotating mechanism of the apparatus of FIG. **1**.

FIG. **3** is a vertical cross-section taken generally along line **3—3** of FIG. **2**.

FIG. **4** is a similar vertical cross-section, but from an opposite view, and as taken generally along line **4—4** of FIG. **2**.

FIG. **5** is a horizontal cross-section of the apparatus of FIG. **1**, as taken generally along line **5—5**.

Corresponding reference characters indicate corresponding parts throughout the views of the drawings.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to the drawings, there is illustrated generally at A a system according to an embodiment of

the invention for carrying out durability or fatigue tests of fluid valves and especially prosthetic heart valves.

System A constitutes a bellows-actuated fluid oscillator for cycling fluid at a frequency of from several hundred to several thousand cycles per minute in a completely closed liquid condition for repeatedly exposing the sample under test to the action of an oscillatory fluid on opposite sides of the sample. The action involves all three of: (1) forces; (2) inertia; and (3) flow.

System A is a closed system, as noted, wherein the fluid utilized as a test medium is not exposed to atmosphere or other oxidizing or non-sterile factors. If the test samples constitute prosthetic heart valves, the test fluid may be sterile human blood plasma heated to a body-simulative temperature, e.g., the normal body temperature 37° C., or other suitable fluids.

Referring primarily to FIG. **1**, a base plate **10** of circular shape in plan is suitably supported by a cylindrical base **12**. Carried centrally by and extending below base plate **10** is a drive motor **16** such as of, for example, controllable speed DC type to provide rotation of its output shaft **18** at a preselected angular velocity. A cylindrical housing **20** extends above base plate **20** for enclosing a swash plate **22** adapted for being rotated by shaft **18** by means of a rotatable tilt coupling **24**, the features of which are described in greater detail below.

A so-called port plate **26** of circular periphery extends across the top of housing **20** and, as will be hereinbelow apparent, is radially ported for fluid communication between bellows **28, 28'** carried by swash plate **22** and valve chambers as at **30, 30'** in which are provided test samples, as at **32, 32'** such as prosthetic heart valves which are to be tested by the repeated oscillatory forces produced by fluid motion relative to such testing samples simulative of the action of blood as it is pumped in the human heart, as produced in passages **29, 29'**.

Extending across the top of test or valve chambers **30, 30'** is a top plate **34** of circular shape and plan, through which is provided a passage **36** for flow of fluid from one test sample, such as **32**, across to the other test sample, **32'**. Thus, it will be understood that a fluid path is completed between the opposite bellows **28, 28'** including fluid passages **31, 31'** in the test fixtures or valve chambers **30, 30'** and also through passage **36**. However, in accordance with the invention, each of said passages **31, 31'** has connected with it a respective radial bypass port **38, 38'** for providing connection to a central bypass passage **40**. Passage **40** is formed by a cylindrical sleeve **42** closed at its bottom end by a bottom wall **44** of port plate **26** and opening at its upper end into a central aperture **46** for communication with passage **36**.

Although but two bellows **28, 28'** and two valve or sample chambers **30, 30'** are shown in FIG. **1**, it will be understood that the invention contemplates the provision of a plurality of such chambers and bellows, such as two, four, six or eight in number, evenly and circularly spaced about the axis defined by motor shaft **18**.

Sleeve **42** constitutes a central bypass chamber to which fluid is selectively admitted from the respective bellows upon rotation of swash plate **22**, compressing each bellows in turn. As each bellows is compressed, fluid is bypassed through throttle valve orifices **48, 48'** which are located in a reduced thickness portion **50** of sleeve **42** and which are adapted to restrict the flow of bypass according to the positioning of sleeve **42** relative to passages **38, 38'**, as explained below. Communicating essentially with bypass passage **36** and also with the bypass chamber **40** is a pressure line or tap **52** for connection with a conventional pressure switch (not shown) such as operative for turning off motor **16** and otherwise disabling apparatus A if the pressure should exceed a predetermined maximum safe value, or decrease below a minimal set value if a leak occurs. Extending into chamber **40** is a temperature sensor **54** for monitoring the temperature within chamber **40** and, thus also, the temperature of the fluid circulating within the system. Also extending into chamber **40** is an electric heater **56** which by conventional control interconnection with temperature probe **54** may be switched on or off cyclically as necessary to maintain the fluid within the apparatus substantially as a predetermined temperature such as normal body temperature at 37° C. The appropriate pressure-responsive switch (not shown) interconnected with pressure tap **52** may be also operative to turn off the source of electric power for heater **56** if the internal pressure should change abnormally, thereby preventing leakage of fluid from the apparatus.

Referring to FIG. **5**, sleeve **42** is centrally located within the port plate **26** and equidistant from each of the passages **29** which receive fluid relative to the bellows **28, 28'**. Passages **38, 38'** extend radially toward sleeve **42** and communicate with bypass chamber **40** of said sleeve through throttle valve control orifices **48, 48'**, which are shown slightly offset relative to the passages **38, 38'**, whereby such orifices are partly blocked by the port plate relative to such passages. Sleeve **42** may be rotationally shifted, when apparatus is partly disassembled on its elements loosened relatively, to move the orifices **48, 48'** more or less into alignment with the passages **38, 38'**. This movement controls the effective size of the orifices and consequently provides greater or lesser closing pressure difference across the valves.

It will be understood that, during operation, pressure developed by the bellows will be such as to cause a net positive flow from the respective bypass passages **38, 38'** into the bypass chamber **40** and thereby such fluid will bypass the test valves **32, 32'**. A bypass pressure differential can thereby be precisely controlled to predetermine the closing valve pressure developed at each test valve during cycles of operation.

Tilt coupling **24** is show in greater detail in FIGS. **2-4**. Generally, coupling **24** is rotatably journalled to swash plate **22** to produce the rotational tilting of swash plate **22** without actual rotation, yet with a controlled degree of tilt, providing a tilt axis Y' relative to normal Y.

The extent of contraction and expansion with each of the bellows **28, 28'** alternately undergoes is thereby predetermined, the coupling **24** being adjustable for this purpose, as explained shortly. FIG. **3** illustrates that swash plate **22** is provided with a ball bearing assembly **58** by which the coupling **24** is journalled to swash plate **22**, producing such tilting.

More specifically, and referring also to FIG. **4**, coupling **24** has a lower half or so-called U-base member **60** which is bored to accept motor shaft **18**. Member **60** is vertically slotted at one side only, as shown at **62**, with such slot extending through to the bore for the motor shaft. Clamping bolt **64** is threaded laterally through the slotted portion of member **60** for clamping it tightly to motor shaft **18**. An upper portion **66** of the coupling is provided with a tongue **67** fitted within a U-shaped recess **68** of portion **60** and is maintained in pivotal relation within recess. Another bolt **72** is threaded through the upper portion **66** at the other end of the

aperture through tongue **67**, but the tongue **67** is slotted, its slot **74** opening downwardly, to permit tongue **67** to pivot upwardly about pivot bolt **70** and to be tilted by an amount determined by a jack screw **76**. After the desired extent of tilt has been achieved by adjustment of jack screw **76**, bolts **64**, **70**, and **72** all are tightened.

Tongue **67** supports a bearing hub **78** having a bearing retainer flange **59**, the hub being fitted within the inner race **80** of bearing **58**. Outer race **82** rotates relative to the inner race **80** over ball bearings **84**, which race **82** is set within a central recess **86** of swash plate **22**. Accordingly, as tilt coupling **24** is rotated by the motor shaft **18**, swash plate **22** is given a rotary-tilt motion without itself rotating. Such motion causes oscillation of the bellows **28**, **28'** to provide pumping action by which each of the test samples are, in sequence, each provided with fluid under pressure and then, on the alternate half of each cycle, are exposed to a negative pressure. Each test valve is thereby cycled during each rotation of motor shaft **18**. Accordingly, the angular velocity of shaft **18** determines the cycle rate of each test valve. As the number of test valves may be as many as four, six, eight, etc., each such rotation of shaft **18** cycles a multiplicity of test samples, and with the displacement drive amplitude being determined by the degree of tilt provided by coupling **24** thereby to predetermine the flow rate through each test valve. As explained above, the pressure to which each test valve is exposed is determined by the positioning of the throttle valve orifices **48**, **48'**.

The novel packing geometry and arrangement of elements thereby provides simultaneous testing of a multitude of test valves, which may be any of various types, but the packing geometry for testing of prosthetic heart valves is such that six testing chambers **31**, **31'** provides an optimum number.

The extreme compactness of new apparatus A greatly minimizes the volume of the testing fluid utilized such as blood plasma or serum. Further, since the fluid is exposed to a limited surface area within the apparatus, there is very little friction as the test fluid oscillates therein, with consequent negligible frictional heating of the fluid. The low fluid and mechanical mass of apparatus A provides oscillation at a relatively high frequency of, for example, 1000–2000 cycles per minute and with very little driving power being required.

Furthermore, the system is completely sealed, there being no contact with the test fluid with the ambient environment. Accordingly, for the durability-fatigue testing of prosthetic heart valves, the new apparatus is extremely advantageous.

In operation, swash plate **22** first undergoes tilting movement from the position shown in FIG. **1**, causing compression of bellows **28**. The test fluid, such as blood plasma, is pumped up into the left valve chamber **31**, thus closing valve **32**, and exits through the bypass port **38** and its associated throttle valve control orifice **48**. The inertial pressure drop through such port or orifice **48** is communicated to the closed valve **32'** and produces closing pressure for the latter. The exit flow thus is through chamber **40** and down through valve **32'** in accordance with the fluid motion shown by arrows in FIG. **1**. Adjustment of sleeve **42** controls the effective cross section of each such orifice. Accordingly, the pairs of test samples alternately undergo closing and opening, inasmuch as the tilt and flow processes are reversed as the rotary-tilt movement of swash plate **22** results in tilting of the plate such as will compress bellows **28'** and elongate bellows **28'**, each as once more shown in FIG. **1**.

In addition to providing a highly useful apparatus, the invention may be noted as also being methodo-logically innovative. Thus, there is provided a new method of durability testing of check valves. Further, the novel use of a swash plate to cause alternate expansion and contraction of the bellows at opposite sides of the swash plate provides an arrangement which is at once suited both for testing only a pair of test samples as well as for multiple pairs of such samples, such as two, four, six, etc., as hereinabove explained, and thereby permitting a single motor to be utilized regardless of the number of test valves.

In view of the foregoing, it will be seen that the several objects of the invention and other advantages are achieved by the new constructions and methods which have been described.

Although the foregoing includes the description of the best mode of the embodiments contemplated for carrying out the invention, various modifications are contemplated.

As various modifications could be made in the constructions and methods herein described and illustrated without departing from the scope of the invention, it is intended that all matter contained in the foregoing description or shown in the accompanying drawings shall be interpreted as illustrative rather than limiting.

What is claimed is:

1. Valve testing apparatus for testing of check valves such as prosthetic heart valves by application of repeated oscillatory flows produced by fluid motion relative to the valves, said apparatus comprising chamber means for receiving a plurality of test samples comprising valves to be tested, said chamber means defining fluid flow passages communicating with the valves for directing an oscillating flow of fluid to said test samples, at least first and second bellows respectively connected with the fluid flow passages, and a swash plate carrying the bellows, means for rotatably driving the swash plate for producing rotatably tilting oscillatory movement of the bellows, and a further fluid passage connecting the test samples for providing a fluid path extending between the bellows and including bypass passage means for receiving fluid from each of the passages respectively communicating with the bellows, and bypass flow control means, for selectively permitting the fluid to bypass the respective test valves through the bypass passages means thereby to control the fluid pressure to which the valves undergoing testing are exposed.

2. Valve testing apparatus according to claim **1** and further characterized by the bypass control means providing for branching of fluid from the respective bellows upon contraction thereof whereby a portion of the fluid flows into and closes a valve undergoing testing and another portion bypasses such valve by flowing through a bypass path, the amount of flow in said bypass path determining the closing pressure for such valve, said bypass path permitting fluid flow also to the inlet of a second one of the valves for ultimate flow into the other of the bellows upon expansion thereof, the bypass path being defined in part by a central bypass chamber.

3. Valve testing apparatus according to claim **2** and further characterized by temperature control means for providing heat transfer with respect to the fluid in said central bypass chamber for maintaining the fluid at a predetermined temperature.

4. Valve testing apparatus according to claim 3 and further characterized by the temperature control means including at least one temperature probe extending into the central bypass chamber, the heat transfer means comprising an electric heater extending into the bypass chamber.

5. Valve testing apparatus according to claim 2 and further characterized by the bypass passage means including individual bypass ports communicating with the fluid flow passages, the central bypass chamber being of volume substantially larger than the fluid flow passages and communicating with each of the individual ports.

6. Valve testing apparatus according to claim 2 and further characterized by the central bypass passage being centrally located relative to the fluid flow passages, bypass flow control means for communicating with respective ones of the individual bypass ports for causing a predetermined inertial pressure differential across the flow control means comprising orifices selectively changeable for controlling restriction of bypass port fluid flow.

7. Valve testing apparatus according to claim 6 and further characterized by said bypass flow control means comprising a cylindrical body including such orifices and changeable by rotation relative to said individual bypass passages for selectively limiting the effective area the orifices.

8. Valve testing apparatus according to claim 1 and further characterized by said means for driving the swash plate comprising a motor and a rotating-tilt coupling interconnecting the motor with the swash plate, the coupling being of adjustable tilt nature for defining a tilt axis for the swash plate to produce a predetermined drive displacement amplitude produced by oscillatory tilting movement of the swash plate upon motor operation.

9. Valve testing apparatus according to claim 8 and further characterized by the rotating-tilt coupling being rotatably journalled to the swash plate, the motor including a shaft carrying the rotating-tilt coupling whereby oscillatory movement of the swash plate is produced upon rotation of the motor shaft, the rotating-tilt coupling producing a tilt axis for the swash plate forming a predetermined angle with the longitudinal axis of the motor shaft.

10. Valve testing apparatus according to claim 2 and further characterized by the chamber means for receiving test valves being spaced at intervals about a circle, the means for rotatably driving the swash plate being an electric motor having a shaft rotating about an axis extending through the center of the circle, the bypass chamber bing defined by a cylindrical body located centrally with respect to the swash plate and connected by individual bypass ports with the respective fluid flow passages.

11. A method of durability testing of check valves such as prosthetic heart valves including positioning of at least one pair of such test valves with opposite orientations proximate the opposite ends of a fluid path for bidirectional exposure to oscillating movement of fluid in the fluid path, including imparting rapid oscillating movement of said fluid in the path with respect to the test valves, and characterized by permitting the fluid to bypass the test valves according to a predetermined inertial pressure differential, thereby to control the pressure of the oscillating fluid forces to which the test valves are exposed upon oscillation of the fluid.

12. A testing method of according to claim 11 and further characterized by the imparting of rapid oscillating movement of the fluid being effected by causing alternate contracting and expanding of bellows at the opposite ends of the fluid path, including locating the bellows at opposite sides of a swash plate, and causing the swash plate to undergo a rotary-tilt oscillatory motion but without causing rotation of the swash plate.

13. A testing method according to claim 12 and further characterized by controlling the amplitude of oscillation of the rotary-tilt motion by changing tilt axis of the swash plate, thereby to control the amplitude of oscillatory movement of the fluid.

14. A testing method according to claim 13 wherein the fluid comprises blood plasma or other suitable fluids and the test samples are prosthetic heart valves.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 4,546,642

DATED : October 15, 1985

INVENTOR(S) : Wilbur M. Swanson

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 8, Claim 14, line 42, "samples" should be ---valves---.

Signed and Sealed this

Thirty-first Day of *December 1985*

[SEAL]

Attest:

DONALD J. QUIGG

Attesting Officer

Commissioner of Patents and Trademarks